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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,694	08/07/2001	Atsushi Suzuki	210377US0	8724

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EXAMINER

UNDERDAHL, THANE E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,694	SUZUKI ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Applicants Arguments— 35 U.S.C § 112

Rejections under 35 U.S.C § 112 are withdrawn in light of applicant's amendments.

Response to Applicants Arguments—Double Patenting

The applicant respectfully argues that the patent 6,310,100 is not patentably distinct from the current application (US Application # 9/922,664). The arguments are based on two items: 1) U.S. Patent # 6, 310,100 requires the addition of glycerol in the composition and 2) does not require chlorogenic or caffeic acid in the composition.

While these arguments were considered and found persuasive for claims 43-45, they were not found persuasive in view of additional prior art from Yokozawa et al. (Phytotherapy Research, 1995) for claims 40-42 and 56-70. In response to 1) the language of claim 1 of '694 states the composition may contain "a suitable excipient or carrier". The CRC handbook of Food, Drugs and Cosmetic Excipients (CRC, 1992) lists glycerol as an acceptable pharmaceutical excipient (page 199). In response to 2) it is already known in the art that compositions of isolated caffeic, chlorogenic and ferulic acids have already been made for ingestion by animals for therapeutic effects (See Abraham, page 16, Table 1, Code D). Yokozawa et al. shows that caffeic acid alone has some antihypertensive properties (page 195, Table 1, Day 18 and Day 24).

The applicants acknowledgement of the provisional rejection is noted.

Claims 40-42 and 56-70 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11

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of U.S. Patent No. 6,310,100 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose treatments for hypertension comprised of ferulic acid or a derivative thereof. The therapeutic compositions comprising ferulic acid and its derivatives may further comprise pharmaceutical products, nutritional supplements or products, and foods. The reference does not specifically claim chlorogenic or caffeic acid in combination with ferulic acid, but in claim 5 it does disclose a composition "consisting essentially of ferulic acid or a derivative thereof, and at least one other anti-hypertensive compound," which would encompass chlorogenic and caffeic acid. One of ordinary skill in the art would be motivated to combine chlorogenic and caffeic acids, which are known anti-hypertensive agents to a composition comprising ferulic acid with the expectation of successful treatment of hypertension with such a composition.

Claims 40-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 11/209672. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are directed to an agent for preventing, improving or treating hypertension. The agent consists of caffeic acid, chlorogenic, and ferulic acid and a component that stimulates the central nervous system. Although the instant claims do not include a component that stimulates the central nervous system, it would be obvious to use compounds such as sugar alcohols because not only do they stimulate the central nervous system, but they improve the taste of the oral composition. One of ordinary skill in the art would be motivated to

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combine the chlorogenic, caffeic acid, and ferulic acid in a composition for treating hypertension because the combination would most likely have additive effects, if not synergistic effects in treating hypertension.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicants Arguments—35 U.S.C § 103

In the response to the applicant's arguments against the rejection under 35 U.S.C § 103 of claims 46-52, 56-65.

The applicant initially argues that the supplementation of food is with isolated or purified ferulic acid and caffeic/chlorogenic acid. While considered, this argument is found not persuasive since Abraham does use isolated ferulic, caffeic and chlorogenic acid purchased from Sigma (page 16, col 2, Chemicals). Also on the same page Abraham supplements food (ground coffee) (Code C+D) with his composition (Code C). In the applicants reiteration of the argument the applicant asserts that the prior art does not teach a composition or methods “which consists of isolated or purified ferulic acid in combination with an isolated or purified chlorogenic and/or caffeic acid (and a carrier or excipient” (page 8 second paragraph). However the wording of the claim 46 does not include a composition that is “consisting of” but “comprising”. The broad interpretation of this claim includes the compounds listed as well as the possibility of other components.

Another argument made by the applicant is the art used in the rejection does not teach the use of the composition to treat hypertension. However, claims 46-52 are

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drawn to compositions and the limitation of claim 46 that the composition has components (a) and (b) "in an amount sufficient to lower blood pressure or suppress a rise in blood pressure when administered to a mammal" is a functional limitation which merely describes a desired result. In the absence of evidence to the contrary, compositions containing the same components are assumed to be the same or obvious over the disclosure in the prior art (M.P.E.P. § 2173.05 and 2183).

Claims 56-65 are drawn to a treatment method for hypertension using the composition of claim 46. In addition to the arguments presented above, the applicant continues to argue that Hsu does not indicate which components of *Crataegus* (hawthorn) are responsible for the treatment of hypertension, nor does Hsu teach a reasonable expectation of success that isolated ferulic, chlorogenic and/or caffeic acid would exert these effects. Once again the language of claim 46 indicates a composition comprising, not consisting of, ferulic, chlorogenic and/or caffeic acid. Abraham teaches such a composition and according to M.P.E.P. § 2183 (D) "is a structural equivalent of the corresponding element disclosed in the specification." Hsu teach that all the listed components of *Crataegus* are active principles, used to treat hypertension. (col 2, line 58 and 61). Also additional prior art by Yokozawa et al. (Phytotherapy Research, 1995) cited above shows that caffeic acid alone has anti-hypertensive properties (page 195, Table 1, Day 18 and Day 24). Since Hsu teach that a composition including chlorogenic acid and caffeic acid is already used in the treatment of hypertension (Hsu, col 2, line 59-61) and Yokozawa et al. shows that caffeic acid alone has some antihypertensive

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properties, a person of ordinary skill in the art would have reasonable expectation of success that the composition of Abraham would treat hypertension.

Claims 46-52, 56-65 stand rejected under 35 U.S.C 103(a) as being unpatentable over Abraham (XP-001148404, 1996) in view of Hsu (US 5,958,417) and further in view of Ghai et al. (US 5,955,269) and additional, new prior art from Yokozawa et al. (Phytotherapy Research, 1995). The claims are to a food supplemented consisting of ferulic acid and caffeic acid, chlorogenic acid or a combination of caffeic acid and chlorogenic acid. Abraham discloses a dietary constituent comprising a combination of chlorogenic acid, caffeic acid and ferulic acid (Table 1). These phenolic compounds occur in some of the commonly consumed vegetables, fruits and beverages (page 19, column 1). Abraham does not expressly disclose that the referenced dietary constituents are used in the treatment of hypertension. However, Hsu ('417) addresses this limitation by disclosing that the active principles, chlorogenic acid and caffeic acid, found in the herbal substance, Crataegus, are used to treat hypertension (column 2, lines 59-61). Yokozawa et al. teach that caffeic acid alone has anti-hypertensive properties (page 195, Table 1, Day 18 and Day 24).

One of ordinary skill in the art would have been motivated to combine the dietary constituents disclosed by Abraham to make a composition for treatment of hypertension as discussed by Hsu because of the need for alternatives to conventional pharmaceuticals currently used to treat hypertension, with an expectation of fewer harmful side effects. Hsu and Yokozawa et al. provide a reasonable expectation of

success by teaching Caffeic acid both in Crataegus and in isolated form have hypertensive properties.

The examiner cites Ghai et al. (US 5, 955,269) that discloses processed foods, or foods fortified with nutraceuticals and the methods of adjusting the combination and level of these nutraceutical compounds in a supplement or in food products to achieve added nutritional or therapeutic benefit (col. 25, lines 1-3, col. 26, lines 43-50 and col. 27, lines 19-25). The reference further teaches that nutraceutical compounds can be administered by inhalation; orally as tablets, capsules, or liquid preparations; controlled release formulations; or as food supplements (col. 25-26). Table 1 (col. 23, lines 41-65) further discloses examples of phenolic acids, such as caffeic, chlorogenic, and ferulic acids as examples of food substances that can be used as nutraceuticals. The reference does not disclose the anti-hypertensive properties of caffeic, chlorogenic, or ferulic acids. However, the teachings of Hsu, as discussed above, do address this limitation. It would have been obvious to one of ordinary skill in the art to combine ferulic acid with chlorogenic acid and caffeic acid as taught by Ghai to obtain synergistic effects in the treatment of hypertension. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a nutraceutical supplement to fortify foods or beverages as taught by Ghai, and to use said foods or beverages in the treatment of hypertension as taught by Hsu, with an expectation of reduced toxicity.

Claim Rejections - 35 USC § 112

The following claim rejections were necessitated by amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-52 and 56-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 46 is indefinite since it fails to provide units for the range of the "ratio of (a)/(b)". The range is "from 0.01 to 50" but without the units (i.e. weight ratio, percent ratio, volume ratio etc.) as a reference the limitation is indefinite. Clarification is required.

Claims 46-52 and 56-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification has no support for un-supplemented food as presented in claim 46.

In summary no claims, as written, are allowed for this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached on 8:00 to 17:00.

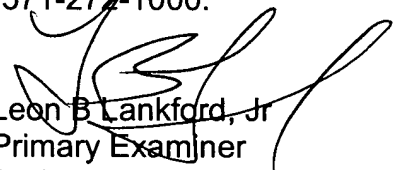
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651